

Research Advisory Committee on Gulf War Veterans' Illnesses

June 16-17, 2003 Committee Meeting Minutes

U.S. Department of Veterans Affairs
810 Vermont Avenue, NW; Room 230
Washington, DC



DEPARTMENT of VETERANS AFFAIRS

**Research Advisory Committee on Gulf War Veterans' Illnesses
VA Eastern Kansas Healthcare System (T-GW)
2200 S.W. Gage Blvd. Topeka, KS 66622**

I hereby certify the following minutes as being an accurate record of what transpired at the June 16-17, 2003, meeting of the Research Advisory Committee on Gulf War Veterans' Illnesses.

/signed/

James H. Binns,

Chairman

Research Advisory Committee on Gulf War Veterans' Illnesses

Table of Contents

| | |
|---|-----------|
| Table of Contents | 3 |
| Attendance Record..... | 5 |
| Abbreviations | 6 |
| Meeting Agenda | 7 |
| Overview - June 16, 2003..... | 9 |
| <i>Physiological and Genetic Aspects of Autonomic Dysfunction in Gulf War Veterans.....</i> | <i>9</i> |
| <i>Effects of Exposure to Multiple Chemicals at Low Dose in vivo: Allowing Physiology into Toxicology.....</i> | <i>10</i> |
| <i>Effects of Pyridostigmine Bromide and PTSD on Neuropsychological Function in GW Veterans</i> | <i>10</i> |
| <i>Effects of Inhalation Exposure to Low Levels of Sarin in Fischer 344 Rats.</i> | <i>11</i> |
| <i>Relationship between Illnesses in Gulf War Veterans and Acetylcholinesterase Levels.....</i> | <i>12</i> |
| <i>Prospective Assessment of Neurocognition in Future Gulf-Deployed and Gulf-Nondeployed Military Personnel</i> | <i>13</i> |
| <i>Public Comments</i> | <i>13</i> |
| Overview - June 17, 2003..... | 14 |
| <i>Committee Staff Update</i> | <i>14</i> |
| <i>Presentation by Secretary of Veterans Affairs, Anthony J. Principi.....</i> | <i>14</i> |
| <i>Presentation by Deputy Secretary for Public Affairs, Jeffrey Phillips</i> | <i>14</i> |
| <i>General Accounting Office (GAO) Report on Plume Modeling of Khamisiyah Exposures</i> | <i>14</i> |
| <i>Review of recent (and recently identified) Gulf War research</i> | <i>15</i> |
| <i>Birth Defects Research</i> | <i>15</i> |
| <i>Discussion of Recommendations for Committee Report.....</i> | <i>15</i> |
| <i>Public Comments</i> | <i>18</i> |
| Appendix A..... | 19 |
| <i>Presentation 1 – Antonio Sastre</i> | <i>19</i> |
| <i>Presentation 2 - John Vogel.....</i> | <i>54</i> |
| <i>Presentation 3 – Roberta White.....</i> | <i>65</i> |
| <i>Presentation 4 – Rogene Henderson.....</i> | <i>77</i> |

| | |
|---|------------|
| <i>Presentation 5 – Nelda Wray</i> | 88 |
| <i>Presentation 6 – Jennifer Vasterling</i> | 91 |
| <i>Presentation 7 – Beatrice Golomb</i> | 95 |
| <i>Presentation 8 – Beatrice Golomb</i> | 101 |
| Appendix B | 109 |
| <i>Public Submission 1 – Albert Donnay</i> | 109 |

Attendance Record

Members of the Committee

James H. Binns, Chairman

Nicola Cherry

Beatrice Golomb

Joel Graves

Robert W. Haley

Marguerite Knox

William J. Meggs

Pierre J. Pellier

Steve Robinson

Steve Smithson

Lea Steele

Consultant to the Committee

Jack Melling

Designated Federal Official

Laura O'Shea

Guest Speakers

Rogene Henderson

Michael Kilpatrick

Keith Rhodes

Antonio Sastre

Jennifer Vasterling

John Vogel

Roberta White

Abbreviations

| | |
|-------|--|
| AMS | Accelerator mass spectrometry |
| AChE | Acetylcholinesterase |
| BChE | Butyrylcholinesterase |
| CNS | Central nervous system |
| CO | Carbon monoxide |
| DoD | U.S. Department of Defense |
| DFP | Diisopropylfluorophosphate |
| GW | Gulf War illnesses |
| IOM | Institute of Medicine |
| LLNL | Lawrence Livermore National Laboratories |
| MCS | Multiple chemical sensitivity |
| MRI | Midwest Research Institute |
| PON | Paraoxonase |
| PTN | Parathion |
| PER | Permethrin |
| PTSD | Post-traumatic stress disorder |
| PB | Pyridostigmine bromide |
| VA | U.S. Department of Veterans Affairs |
| VABHS | VA Boston Healthcare system |

Meeting Agenda

Research Advisory Committee on Gulf War Veterans' Illnesses
Committee Meeting, June 16-17, 2003

June 16, 2003
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC
Room 230

| | | |
|------------|--------------------------------------|---|
| 8:30 a.m. | Welcome | Mr. James Binns |
| 8:40 a.m. | Research Presentation | Antonio Sastre, Ph.D. Midwest Research Institute Kansas City, MO |
| 10:10 a.m. | Discussion | |
| 10:45 a.m. | Break | |
| 11:00 a.m. | Research Presentation and Discussion | Roberta White, Ph.D., Boston Environmental Hazards Center, Boston, VA Healthcare System Medical Center, Boston, MA |
| 11:30 a.m. | Research Presentation | John Vogel, Ph.D. Lawrence Livermore National Laboratories, Lawrence, CA |
| 12:15 p.m. | Discussion | |
| 12:45 p.m. | Lunch | |
| 1:45 p.m. | Research Presentation | Rogene Henderson, Ph.D. Lovelace Respiratory Research Institute Albuquerque, NM |
| 2:30 p.m. | Discussion | |
| 3:00 p.m. | Summary Discussion | |
| 3:30 p.m. | Break | |
| 3:45 p.m. | VA Research Update | Nelda Wray, M.D. Chief R&D Officer, Department of Veterans Affairs |
| 4:15 p.m. | Ongoing Research | Jennifer Vasterling, Ph.D. South Central MIRECC VAMC, New Orleans, LA |
| 4:45 p.m. | Public Comments | |
| 5:15 p.m. | Adjourn | |

Tuesday, June 17, 2003
811 Vermont Ave.
Room 819

| | | |
|------------|---------------------------------|-------------------------------------|
| 8:30 a.m. | Committee Staff Update | Dr. Beatrice Golomb; Dr. Lea Steele |
| 8:45 a.m. | New Research Update | Dr. Beatrice Golomb |
| 9:30 a.m. | GWVIS Update | Mr. Steven Robinson |
| 9:45 a.m. | Public Affairs | Mr. Jeffrey Phillips, DASD |
| 10:00 a.m. | Break | |
| 10:15 a.m. | Presentations on Plume Modeling | Suchil Sharma, Ph.D., GAO |
| | | Michael Kilpatrick, M.D., DOD |
| | Discussion | |
| 11:30 a.m. | Lunch | |
| 12:30 p.m. | Recommendations Discussion | |
| 2:30 p.m. | Break | |
| 2:45 p.m. | Work Plan | |
| 3:15 p.m. | Public Comments | |
| 3:45 p.m. | Adjourn | |

Overview - June 16, 2003

Chairman James Binns opened the meeting with thanks to the presenters and committee members for the work that went into preparing the meeting. Mr. Binns introduced Dr. Antonio Sastre.

Physiological and Genetic Aspects of Autonomic Dysfunction in Gulf War Veterans.

Antonio Sastre, PhD

Chief Life Scientist, Midwest Research Institute (MRI), Kansas City, MO

Dr. Sastre presented for the first time results of his Department of Defense-sponsored study encompassing tests of autonomic nervous system function in ill veterans compared to well counterparts. Some scientists had previously suggested that Gulf War illnesses (GWI) may be neurological in nature, but studies suggesting neurological problem had often relied on symptoms reported by the veterans themselves. Because ill veterans tested as normal on routine neurological tests, some scientists have pointed to the absence of “objective evidence” of neurological dysfunction.

Dr. Sastre stated that his research is important because it provides objective indicators of neurological dysfunction in ill Gulf War veterans and potentially provides a physiological basis for many of the symptoms associated with GWI. He discussed in detail the importance of the study design and methods used. (See Appendix A – [Presentation 1.](#))

Dr. Haley of the Committee pronounced it an excellent example of how to conduct research. He noted the importance of basing the research on a previous epidemiological study, the Kansas study, so that this expensive process did not have to be repeated, of choosing subjects with defined problems rather than testing random veterans who happened to come in for help, and of using a multidisciplinary team to pick the correct tests to perform. He indicated that PON-1 genetic variability may prove to be more important than BChE.

Dr. Pellier commented that the study was very important because it establishes at least one physiological basis for GWI.

Mr. Binns asked Dr. Sastre whether his findings suggest any promising treatments or future research topics. Dr. Sastre responded that discussion of treatments would be speculative now. Follow-on research direction was clear, however. It is necessary to assess where in the autonomic nervous system “loop” the problem is occurring. For example, take the case of the response in heart rate and blood pressure that is supposed to occur when a person stands up. Is the brain receiving the right sensory data? Is the information being conveyed to the brain correctly, but is the brain interpreting the information or processing it incorrectly? Is the brain processing correctly, but are the commands being sent to the heart the correct ones? Or are all the brain commands correct, but is the problem in the heart or in the arterioles? Understanding the specific nature of the ANS pathology requires studies that can “open the loop”, as physiologists might say, to identify each ANS component individually. These studies can be performed using well-recognized FDA-approved procedures.

A member of the Committee asked if a veteran failed several tests of autonomic function, might it then be possible to conclude that the veteran was autonomically impaired? Which tests would be most instructive if you could just do a few tests on a large number of veterans?

Dr. Sastre said that if only one test could be given, it would be the upright tilt test. It produced the most information on differences between ill and healthy veterans. But it would be necessary to do other tests, too.

Mr. Binns introduced Dr. John Vogel.

Effects of Exposure to Multiple Chemicals at Low Dose *in vivo*: Allowing Physiology into Toxicology

John S. Vogel, PhD

Senior Research Scientist, Lawrence Livermore National Laboratory (LLNL),
University of California

Dr. Vogel's presentation covered two main areas: 1) a study on low levels of pesticide exposure, and 2) technology that can be applied in studying metabolic underpinnings of diseases or syndromes. (See Appendix A – [Presentation 2.](#)) He emphasized that interactions of compounds at extremely small concentrations were physiological but were observable only in whole animals (as opposed to *in vitro* studies). He also suggested that the types of technology being utilized at Lawrence Livermore to detect these interactions may be useful in understanding Gulf War illnesses, and that metabolomic-type approaches could provide hypotheses relating to pathophysiological processes underlying these conditions.

In response to questions by the Committee, Dr. Vogel elaborated that metabolomics could be used to distinguish compounds found in pre- and post-deployment blood samples. While it might be too late to identify evidence of the exposures themselves, one might be able to detect effects of previous exposures.

Mr. Robinson noted that samples of blood from nine hundred Marines were taken and stored before and after the Gulf War, and that many of these Marines would still be alive.

Dr. Sastre observed that metabolomics can be difficult to apply.

Mr. Binns asked how relevant the pesticide exposures used in the study was to real-world conditions. Dr. Vogel said that the level was exceedingly relevant, the equivalent of pesticide exposure that occurs when a human ingests a commercially grown apple.

Chairman Binns introduced Dr. Roberta White.

Effects of Pyridostigmine Bromide and PTSD on Neuropsychological Function in GW Veterans

Roberta White, PhD

Boston VA Healthcare System Medical Center – Environmental Hazards Center

Dr. White presented results of a study conducted at VA's Boston Environmental Hazards Research Center on the role of pyridostigmine bromide and PTSD on neuropsychological function in treatment-seeking Gulf War veterans. (See Appendix A – [Presentation 3.](#)) The results of the study indicated that Gulf War veterans performed worse than nondeployed veterans on measures assessing attention, motor and visuomotor skills, visual memory, and mood and motivation. The study also indicated that: 1) PTSD diagnosis was significantly associated with mood indices, but not significantly associated with cognitive functioning; 2) self-reported PB use was significantly associated with executive system functioning; and 3) there were no interactive effects of PB use and a diagnosis of PTSD in this group of veterans.

In response to Committee members' questions, Dr. White discussed follow-up studies of the Ft. Devens cohort, issues concerning treatment-seekers vs. non-treatment seekers, vulnerability/risk factors and future directions for research. She reported that when veterans in her study were followed up, they perceived their symptoms as worsening over time, and that they performed worse on neuropsychological tests.

Chairman Binns introduced Dr. Rogene Henderson.

Effects of Inhalation Exposure to Low Levels of Sarin in Fischer 344 Rats.

Rogene Henderson, PhD

Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. Henderson presented results of three studies relating to neurological and immunological effects of subclinical exposures to inhaled sarin, conducted at Lovelace Respiratory Research Institute. (See Appendix A – [Presentation 4.](#))

Following Dr. Henderson's presentation, she was asked what markers might be looked for in ill veterans. She said that sarin induces the expression of cytokines in the brain. She also noted that some compounds can be transferred from the olfactory bulb directly into the brain.

Mr. Binns asked what follow-on research Dr. Henderson foresaw doing in response to these findings. Dr. Henderson replied that there was a great deal they should be doing, but that there was presently no funding to follow up.

Mr. Robinson said that there was \$50 million for research in the Assistant Secretary for Health Affairs budget at the Department of Defense that is not being spent.

Mr. Binns asked about possible treatment implications of this research. Dr. Henderson replied that it provided basic information that might, with additional research, ultimately lead to identification of treatments.

Mr. Binns opened the discussion to include all research studies presented that day.

Dr. Haley speculated as to whether Gulf War illness could simply be a permanent case of reduced muscarinic receptors.

Dr. Melling noted that Dr. Henderson's study together with Dr. Sastre's study provided very convincing evidence of the reality of Gulf War illness and the involvement of the autonomic nervous system.

Dr. Meggs noted that research presented at a Japanese meeting earlier in the year had shown long-standing cognitive deficits after organophosphate exposures, in situations where there was no stress present.

Dr. Haley noted that it was critical to do follow-up studies. It might just be necessary to stimulate reactivation of the muscarinic receptors. He indicated he had not seen a loss of brain cells in his research.

Dr. Meggs noted a disturbing progression of the illness. Research should look at the animals over time, and try to determine how to arrest the process.

Dr. Sastre stated that PTSD could affect the autonomic nervous system. He cautioned that a binding site is not necessarily coupled to a G-protein or that they might have been coupled prior to the insult.

Dr. White said that neuroimaging research has shown structural differences in subgroups of ill Gulf veterans. A study supported by the CDC showed a lower volume of white matter in veterans with a high level of complaints. Usually, one would expect to see lesions, but not lower volume. She also suggested there is a need to incorporate information on genetic risk factors. Gulf War illness is a very complex issue and she indicated an interest in doing additional studies on the Ft. Devens cohort.

Dr. Sastre observed that earlier studies of PB showed very low levels of side effects. It was also tested with heat. However, the test conditions were nothing that resembled battlefield conditions or where exposures like pesticides were present.

Mr. Graves said that he experienced no side effects from PB at the time he took the pills. Would it be possible to detect effects now?

Dr. Vogel said that the tools they have at LLNL could help with quantification of these studies. They have done AMS work with humans, and can also do studies on brain fluids.

Mr. Graves observed that the Committee is narrowing down what is happening in Gulf War illness.

Relationship between Illnesses in Gulf War Veterans and Acetylcholinesterase Levels

Dr. Nelda Wray, MD, MPH

Chief Research and Development Officer, Department of Veterans Affairs

Dr. Nelda Wray provided a research update on a collaborative study between VA and Dr. Hermona Soreq investigating acetylcholinesterase (AChE) levels in Gulf War veterans. (See Appendix A – [Presentation 5.](#)) The study had been undertaken and fast-tracked in response to a suggestion by the Committee following a presentation made by Dr. Soreq at the February, 2003, Committee meeting. Dr. Wray anticipated that preliminary results of the study would be available the coming summer.

In discussion following the report, a Committee member reminded Dr. Wray that the Committee's interest in Dr. Soreq's work was to determine whether an atypical variant form of AChE, AChE-R, was present in abnormally high levels in symptomatic Gulf War veterans, as opposed to AChE levels.

Prospective Assessment of Neurocognition in Future Gulf-Deployed and Gulf-Nondeployed Military Personnel

Jennifer Vasterling, PhD

South Central MIRECC VA Medical Center, New Orleans, LA

Dr. Vasterling provided information about a study recently initiated at the VA Medical Center in New Orleans that will provide assessment of neurocognitive function among military personnel before and after deployment to Iraq, and in a comparison group of nondeployed veterans. (See Appendix A - [Presentation 6.](#)) Discussion followed concerning the importance of prospective data collection.

Public Comments

Mr. Binns invited members of the public who had signed in to address the Committee.

Mr. Dan Fahey addressed the subject of depleted uranium (DU), a topic he has been following since 1993. He expressed concern that government representatives had lied about the occurrence of lymphoma identified in a Gulf veteran who had embedded depleted uranium fragments. He also voiced concern that government was only studying a small number of cases of DU-exposed veterans. He recommended a study of the 900 veterans identified by the Department of Defense as having been highly exposed to DU. He also said it is likely that some personnel in the current Iraq war are being exposed to DU but that the VA brochure does not mention DU or the availability of DU testing in its notification to veterans.

Ms. Denise Nichols made several recommendations to the Committee.

1. Keep up the website: schedules, Power Point presentations from meetings, etc.
2. VA clinicians need access to the website, to the Secretary's videotape.
3. Diagnostic data should be collected from VA: blood flow, heart rate. What are the rates of ICD-9 codes?
4. The Committee should consider the work of leading clinicians, not just researchers, including Dr. William Rae and Dr. David Berg.
5. Intravenous drips of glutathione has proved helpful, also CoQ10.
6. Look at magnesium levels, other data not considered by VA clinicians.

Mr. Albert Donnay noted that VA paid no attention to multiple chemical sensitivity (MCS), despite the condition being identified by VA as a major illness among Gulf War veterans in Dr. Kang's 1998 study. He indicated that the study had shown that 15% of ill veterans have MCS vs. 5% of controls. By contrast, VA did look for chronic fatigue syndrome and fibromyalgia in ill Gulf War veterans, although fewer veterans reported these conditions.

Mr. Donnay discussed carbon monoxide (CO) as a possible cause of Gulf War illness. He said that when he has checked the breath of ill veterans, all have had elevated levels of CO. He stated that oxygen therapy is an effective treatment for CO. He said that normobaric oxygen works fine, as documented in German research. He had been working with six civilian doctors using oxygen to treat MCS. Dr. Rae uses oxygen for 19 days, which is not long enough in these doctors' experience. Mr. Donnay noted that Dr. White has published on MCS in Gulf War veterans and CO poisoning in civilians. He submitted a written statement. (See Appendix B – [Public Submission 1.](#))

Mr. Binns adjourned the first day of the meeting.

Overview - June 17, 2003

Committee Staff Update

Chairman Binns opened the meeting by giving the Committee a staffing update. The roles of Dr. Lea Steele and Dr. Beatrice Golomb were discussed. Dr. Golomb will now be concentrating on the science and will no longer be responsible for committee staff administration. Dr. Steele will be joining the staff as its scientific director, providing full time leadership for the committee staff beginning in September. The committee staff operation is moving from San Diego to Topeka. In comparison to the current operation, three times the level of scientific expertise will now be available to interface with the scientific community.

Presentation by Secretary of Veterans Affairs, Anthony J. Principi

Secretary of Veterans Affairs Anthony J. Principi addressed the Committee. He expressed his frustration with the current level of understanding of Gulf War illnesses, and indicated he is hopeful that the Committee will make important contributions in this area. He stated that he has asked the Institutes of Medicine to study further the long-term effects of low-level exposures to sarin nerve gas.

Presentation by Deputy Secretary for Public Affairs, Jeffrey Phillips

Deputy Secretary for Public Affairs, Jeffrey Phillips, played Secretary Principi's videotaped appeal to VA researchers to submit proposals for studies to study Gulf War illnesses. For FY2004, twice the level of VA funding would be available for this type of research, as compared to any previous year. Mr. Phillips said the tape would be widely publicized and disseminated within the VA community. All physicians and researchers would have the opportunity to view the tape using streaming video on the web, VA's satellite television system, or hard copies distributed to VA medical centers.

General Accounting Office (GAO) Report on Plume Modeling of Khamisiyah Exposures

Keith Rhodes

U.S. General Accounting Office

Mr. Rhodes presented a preliminary report on GAO's ongoing assessment of DoD plume modeling of the dispersion of chemical agents resulting from the U.S. demolition of Iraqi chemical munitions at Khamisiyah, Iraq, in March of 1991. The GAO investigation determined that several aspects of DOD's most recent modeling effort had neglected to consider important factors or had been based on unsupported assumptions and therefore could not be supported as being reliable or definitive. Mr. Rhodes indicated that in light of this information, it was not possible to know with any accuracy the total number or which individuals were or were not exposed to chemical agents as a result of the Khamisiyah demolitions. He also suggested that sufficient data are not available to produce an adequate model, and that epidemiologic studies that had relied on plume modeling efforts were not likely to have produced valid results.

Dr. Michael Kilpatrick, Deputy Director of the Deployment Health Support Directorate at the Department of Defense, responded that since the GAO findings were preliminary and DoD had not had an opportunity to review the final report, he could not comment on the GAO presentation. He described the modeling choices made by DoD analysts with respect to the Khamisiyah plume.

There was a discussion among Committee members about whether the Committee should compose a recommendation to the Secretary in regard to problems that may have resulted from VA researchers who had published studies, which relied on Khamisiyah modeling data that may have been inaccurate, and therefore led to erroneous conclusions. It was ultimately agreed to wait until the GAO report is available in final form before making any related recommendations.

Review of recent (and recently identified) Gulf War research

Dr. Golomb gave a presentation summarizing new Gulf War illness-related research published since the last meeting. (See Appendix A – [Presentation 7.](#))

Birth Defects Research

Dr. Golomb presented a report on research on the prevalence of birth defects in children of Gulf War veterans. (See Appendix A - [Presentation 8.](#))

Discussion of Recommendations for Committee Report

Mr. Binns stated that feedback from Committee members on the draft report indicated that it required further work. It was essential that the report provide a clear statement of the relevant science. This effort would require taking advantage of the new Committee staff resources, which would not be in place until September. Meanwhile, it was also desirable for the Committee quickly to get draft recommendations in front of VA decision-makers who will be considering FY2005 budgeting decisions and FY2004 research funding decisions. A draft executive summary including the recommendations should be completed by the staff and provided to the Secretary in the next six-to-eight weeks. The Committee will be asked to review and comment on the preparation of the draft executive summary. The full report is expected to be available early in 2004.

Mr. Binns said that recommendation topics to be further considered today include birth defects, vaccines, and research priorities. He presented the draft recommendations on birth defects from the current draft of the report, as follows:

- 1) Follow-up analysis and research should determine rates of birth defects in ill Gulf War veterans (not just all Gulf War veterans), and in subgroups of ill veterans
- 2) Continued surveillance for birth defects in children of Gulf War veterans should be conducted. Questions on children's health should be incorporated in surveys of Gulf War veterans.
- 3) Such research should look at the health of children of all ages, not just up to one year, including learning and behavioral disorders.
- 4) VA should closely follow and consult with the investigators of the ongoing British study of birth defects in Gulf War veterans, which appears to incorporate these recommendations.

Dr. Cherry commented that the risk of birth defects in the studies reviewed by Dr. Golomb was very low. Dr. Golomb said that there was a need, however, to look at older children for health problems including behavioral disorders, which has not been done.

Dr. Pellier said that there was generally less risk in having children earlier, before the chromosomal risk goes up. Dr. Haley also noted the risk was low. Dr. Pellier observed that there are toxicology studies for acetylcholinesterase-inhibiting drugs.

Dr. Golomb stated that there were many articles that suggested that these types of problems were associated with acetylcholinesterase inhibitors.

Mr. Robinson suggested that the Committee hear from Ms. Betty Mekdici, who maintains a birth defects registry.

Dr. Cherry suggested inviting the British researchers who are studying birth defects in Gulf War veterans to present their results before the Committee.

Dr. Haley noted that Dr. Kang's study is currently validating the existence of reported birth defects through a review of actual medical records. There may be opportunity to get additional analysis from this study population. Dr. Kang's data should be made available to other researchers. Results of the additional analyses from the Kang study should be made available to the public. Mr. Graves suggested that the birth defect data assembled by Dr. Kang should be analyzed by unit.

Dr. Melling cautioned that the language of the recommendation with respect to the risk for birth defects should not be unduly alarming, given the reported research results. Dr. Cherry agreed. There were no indications, based on existing studies, that there was a reason for veterans to not have children because of concerns related to an increased risk of birth defects.

Dr. Meggs said that future studies should look for increased levels of illnesses in veterans' offspring.

It was agreed to incorporate the consensus of the Committee's comments in the recommendations, for further review by the Committee.

Mr. Binns presented the draft recommendations pertaining to vaccines. Research should compare the health experiences of military units shipped the anthrax vaccine and units not shipped the anthrax vaccine on topics such as:

- Who is sick
- Cytokine profiles
- Any acute reaction at the time of vaccination
- Squalene antibodies, including studies of ill veterans versus well veterans

The recommendations were discussed and commented upon as follows:

- Similar follow-up studies should be conducted of veterans who received the anthrax vaccination at Dover Air Force Base, as well as at Tripler, and in Korea. Details of existing epidemiological studies related to use of the anthrax vaccine should be made public. There should be a randomized trial of the new anthrax vaccine and health questions pertinent to symptoms affecting Gulf War veterans should be added to vaccine studies currently being planned by federal agencies.

- Comprehensive records of all vaccinations administered by the military should be kept, and active surveillance should be conducted for both short-term and long-term effects, including outcome measures sensitive to cognitive changes.

- While research regarding new vaccines is important for the public good and to the health of future military personnel, it is less important to Gulf War illnesses research than, for example, studies into neurological mechanisms involved in Gulf War illnesses. Funding for studies of the effects of vaccines not used during the Gulf War should therefore not come from the “up to \$20 million” available in FY2004. An appropriate source for funding in this area might more rightly come from unspent medical research funds believed to be available at DoD.

- The possibility of studying possible adverse effects of receiving multiple simultaneous vaccines was discussed. The Committee would look at results reported in the Australian study on this topic. Researchers could collect the blood of returning veterans from Iraq and study markers of immune status. Shot records are now computerized.

A revised draft of the recommendations related to vaccines, reflecting Committee members’ above comments, would be prepared for review by the Committee.

Mr. Binns stated that the next topic to be discussed was research priorities and objectives.

There was strong agreement among Committee members that Gulf War illnesses research should be given priority among projects to be funded under the Secretary’s special FY2004 deployment health research initiative. In comparison with any other recent deployment, there were more deployed to the Gulf War, more became ill as a result of deployment, and the need for additional research was great because the mechanisms and treatments for these illnesses are not understood. This research is also potentially of great relevance for future deployments. Moreover, as a result of recent research, promising opportunities for research breakthroughs have been identified, and scientists could take advantage of these opportunities. Therefore, it was reasonable that the lion’s share of the \$20 million to be allocated for Gulf War illnesses research. A similar or higher amount should be budgeted for FY2005. The Committee also encouraged other initiatives that would benefit ill Gulf War veterans.

Within Gulf War illnesses research, treatments research should be given the highest priority. Only VA has the patient population needed to study treatments. The Treatment Development Center(s) conceptualized by the Committee should be established and funded at \$2.5 million in FY 2004 and \$4.0 million in FY2005. Goals should be set to have eight treatments under data development by the end of FY2004 and two treatments in clinical trials. Small-scale trials should be used to avoid spending all funds on one trial.

The federal government, including VA, should prioritize the use of research resources for studies in areas that show the most promise, emphasizing research topics in which breakthroughs had been made and on scientists who had developed promising preliminary work. Examples of topics to pursue include markers, neurological mechanisms, effects of acetylcholinesterase inhibitors, and genetic linkages to Gulf War illnesses. Examples of laboratories to support include those at the U.S. Army Institute of Chemical Defense, Lovelace Respiratory Research Institute, and Lawrence Livermore National Laboratory.

An example of a topic not to pursue is stress. While physiological stress and psychological factors are important subjects for research as relate to deployment health in general, and some studies suggest that stress can increase the effects of toxic exposures, research proposals into the illnesses of Gulf War

veterans should not be funded if their primary focus is on psychological stress or other psychological causes of illness.

Research should pursue new technologies for identifying effects of low-level chemical exposures and detecting physiological abnormalities underlying Gulf War illnesses. Examples might include technologies such as those described by Dr. Vogel at Lawrence Livermore, Dr. Soreq in Jerusalem, and proteomics and/or genomics research.

Recent research emerging from the study of Gulf War illnesses also has important implications for chemical defense. There is currently a \$1.6 billion annual investment at NIH in medical defenses against bioterrorism. There should be a comparable effort to develop safe and effective treatments against chemical agents.

Public Comments

Ms. Denise Nichols supported the idea that additional study should be done of birth defects. She also endorsed the proposed treatment research recommendations. She advocated posting the Committee's work plan on its website and otherwise using the website to make information about research and the activities of the Committee more open.

Dr. Rich Van Konynenburg noted that he had attended the last meeting of the Committee and had submitted a paper on the importance of glutathione. He thought this supplement had improved the health of chronic fatigue and fibromyalgia patients, although it was not a cure. It is possible to test for glutathione levels. Doctors using glutathione therapy include Paul Cheney, MD, Grace Ziem, MD, and Patricia Salvato, MD.

Mr. Scott Walker noted that he had attended the last meeting of the Committee and spoken about the increased absorption of vitamin and mineral supplements when taken in liquid form. He presented written results of a survey of ill veterans who used supplements provided by Mr. Walker. Of twenty-two summaries returned by veterans, twenty-one reported improvement. These results demonstrate that nutrition should be considered as a treatment for Gulf War illnesses.

Mr. Binns adjourned the meeting.